Stacey Bonnell, MBA, RAC

SUMMARY

Dynamically evolved leader with diversified experience in regulated medical industry; working to proactively shape the orthopaedic ecosystem to efficiently bring innovative healthcare solutions to patients.

PROFESSIONAL EXPERIENCE

FDA Medical Device Advisory Committee (MDAC) ***term 9/2020-9/2024***

Appointed non-Voting Industry Representative serving the Orthopaedic and Rehabilitation Devices Panel

- Representing perspectives of industry (majority) as one of seven standing members of Committee responsible for assessing the safety and efficacy of products (including classifications, generic and specific device type issues of risk).

Orthopedics Surgical Manufacturers Association **(OSMA)**

Current Past President, Board of Directors ***01/01/2023 to Present***

- Leading advocacy initiatives across industry in collective effort to influence regulations for the betterment of ecosystem and patients. Diplomatically representing industry in persuasive endeavors toward appropriate regulation.

Nuvasive, Inc. **San Diego, CA**

Global Leader, Regulatory Affairs ***07/2021 to Present***

- Responsible for oversight of all regulatory activities for developed and in-development orthopaedic technologies; attainment & maintenance of product licensure globally.
- Leading a global high-performing team of Regulatory experts serving internal & external innovation partners with dynamic regulatory strategies.

DePuy Synthes Orthopaedic companies of Johnson & Johnson **West Chester, PA**

Director, Regulatory Affairs–Trauma Upper Extremity / Biomaterials & Front-End Innovation **11/01/2018 *to* 06/2021**

Associate Director, Regulatory Affairs Biomaterials & Front-End Innovation 01/01/2016 to 11/01/2018

Senior Manager, Regulatory Affairs Biomaterials & Front-End Innovation 09/01/2015 to 01/01/2016

Manager, Regulatory Compliance Outreach/Compliance Lead **07/06/2014 *to* 08/31/2015**

Manager, Regulatory Affairs **DePuy Synthes Spine** **02/01/2013 *to* 07/05/2014**

Synthes Spine, USA **12/01/2003 *to* 02/01/2013**

Senior Regulatory Affairs Specialist *01/2011 to 02/2013*

Regulatory Affairs Specialist *04/2008 to 12/2010*

Associate Regulatory Affairs Specialist *06/2006 to 04/2008*

EDUCATION

J&J Regulatory Affairs Advanced Leadership course – "***elevAte***" [class co-Lead] 2017

The Pennsylvania State University, Great Valley School of Graduate Professional Studies

- Masters of Business Administration & Post-baccalaureate Certificate in Business 2008

The Pennsylvania State University, University Park Campus 2002

PROFESSIONAL ASSOCIATIONS/ MEMBERSHIPS

Orthopedics Surgical Manufacturers Association [OSMA] member since 2008

- Co-Founded OAR: 1st FDA Ortho Collaborative Community August 2022
- Chair OSMA Anti-Infective Working Group 2020-present

Advamed Working Groups: Orthopaedic, Pediatric, & Combination Products 2015-2021

Advanced Medical Technology Association [AdvaMed] 2008-2021

Medical Device Manufacturers Association [MDMA] collaboration 2019-present

American Academy Orthopaedic Surgeons [AAOS] collaboration 2016-present

Regulatory Affairs Professional Society Member [RAPS] + RAC member since 2003

- podium representation w/ FDA & Notified Bodies (TUV SUD, & BSI) 2016 & 2019 RAPS Convergence

Authorship

1. Co-authored abstract entitled, "*A Mock Submission to Initiate a Medical Device Clinical Trial Using Modeling and Simulation*"; ASME 2018.
2. Co-authored abstract entitled, "*Infection Innovation*"; published in ODT Magazine September 1, 2022.
3. Co-authored White Paper entitled "*Up-classification of spinal implants in the European Union: MDCG 2021-24: Risk-based approach?*" with Dr. Bassil Akra & OSMA Working Group; publication date imminent (Q2, 2023).